



ENZYMATIC THERAPY INCORPORATED

*What **Better** feels like.™*

INTEGRATIVE THERAPEUTICS INC.™
NF Formulas • PhytoPharmica
Tyler Encapsulations • Vitaline Formulas

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ENZYMATIC THERAPY™
&
PHYTOPHARMICA™

825 Challenger Drive, Green Bay, WI 54311-8328

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October 22, 2004

Office of Nutritional Products, Labeling &
Dietary Supplements, HFS 810
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
PSI Nighttime	Used clinically for over 15 years, PSI Nighttime is NF's original, time-tested PSI formula, which incorporates white willow bark, black cohosh, and wild yam, as well as standardized extracts of valerian, hops, and passionflower. These herbs are combined with minerals and bromelain. The result is an effective relaxation formula that supports normal musculoskeletal function and reduces pain and stiffness due to occasional overuse.*	Niacin (as niacinamide), Vitamin B6 (as pyridoxine hydrochloride), Calcium (as calcium carbonate), Magnesium (as magnesium oxide), Copper (as copper gluconate), Potassium (as potassium chloride), White Willow bark (Salix alb a), Bromelain, Passionflower flower (Passiflora incarnata), Valerian root (Valeriana officinalis), Wild Yam root (Discorea villosa), Black Cohosh root (Actaea racemosa), Hops strobile (Humulus lupulus), Valerian root (Valeriana officinalis) (2% valerenic acid), L-Glutamic acid hydrochloride

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 10/22/04

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